

§ 522.535

(b) *Sponsor*. See 064288 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Horses and ponies*—(i) *Amount*. One implant per mare.

(ii) *Indications for use*. For inducing ovulation within 48 hours in estrous mares with an ovarian follicle greater than 30 millimeters in diameter. Follicular size should be determined by rectal palpation and/or ultrasonography prior to treatment.

(iii) *Limitations*. Administer subcutaneously in the neck. Not for use in horses or ponies intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 44383, Aug. 19, 1998]

§ 522.535 Desoxycorticosterone pivalate.

(a) *Specifications*. Each milliliter of sterile aqueous suspension contains 25 milligrams of desoxycorticosterone pivalate.

(b) *Sponsor*. See No. 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Dosage requirements are variable and must be individualized on the basis of the response of the patient to therapy. Initial dose of 1 milligram per pound (0.45 kilogram) of body weight every 25 days, intramuscularly. Usual dose is 0.75 to 1.0 milligram per pound of body weight every 21 to 30 days.

(ii) *Indications for use*. For use as replacement therapy for the mineralocorticoid deficit in dogs with primary adrenocortical insufficiency.

(iii) *Limitations*. For intramuscular use only. Do not use in pregnant dogs, dogs suffering from congestive heart disease, severe renal disease, or edema. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 13122, Mar. 18, 1998]

§ 522.536 Detomidine hydrochloride injection.

(a) *Specification*. Each milliliter of sterile aqueous solution contains 10

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milligrams of detomidine hydrochloride.

(b) *Sponsor*. See 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. For sedation, analgesia, or sedation and analgesia: 20 or 40 micrograms per kilogram (0.2 or 0.4 milliliter per 100 kilogram or 220 pounds) by body weight, depending on depth and duration required.

(2) *Indication for use*. As a sedative and analgesic to facilitate minor surgical and diagnostic procedures in mature horses and yearlings.

(3) *Limitations*. For sedation administer intravenously (IV) or intramuscularly (IM); for analgesia by IV; for both sedation and analgesia by IV. Do not use in horses with pre-existing atrioventricular or sinoauricular block, with severe coronary insufficiency, cerebrovascular disease, respiratory disease, or chronic renal failure. Do not use in breeding animals. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[54 FR 50365, Dec. 6, 1989; 54 FR 51551, Dec. 15, 1989]

§ 522.540 Dexamethasone injection.

(a)(1) *Specifications*. The drug is a sterile aqueous solution. Each milliliter contains 2 mg of dexamethasone.

(2) *Sponsor*. See Nos. 000061 and 059130 in § 510.600(c) of this chapter.

(3) *Conditions of use*. (i) The drug is indicated for the treatment of primary bovine ketosis and as an anti-inflammatory agent in dogs, cats, cattle, and horses.¹

(ii) The drug is administered intravenously or intramuscularly and dosage may be repeated if necessary, as follows:¹

(a) Canine—0.25 to 1 mg.

(b) Feline—0.125 to 0.5 mg.

(c) Equine—2.5 to 5 mg.

(d) Bovine—5 to 20 mg depending on the severity of the condition.

(iii) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition